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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,284	11/30/2001	Charlotte Horsmans Poulsen	674523-2012	5487

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EXAMINER

NASHED, NASHAAT T

ART UNIT PAPER NUMBER

1652

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 21-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

☐ Amended Specification (PTO 800)

☐ Interview Summary (PTO-413)

The application has been amended as requested in the communication filed February 25, 2004. Accordingly, claims 17-20 have been canceled, and claims 5, 22, 24, 26, 28 and 29 have been amended.

Claims 1-16 and 21-29 are pending and under consideration in this Office action.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-Reference to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

While the exact format of the application is not required as stated above, the various elements should be labeled and present in the specification. The application for example contains Figure 1, but it does not contain a figure description, which is required, see below for further details.

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The

descriptive, preferably from two to seven words may not contain more than 500 characters.

- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

- (e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems

Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (k) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed

in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim for the reasons set forth in the prior Office action, mailed November 25, 2003.

In response to the above objection, Applicants traverse the objection on the ground that claim 4 is properly dependent on claim 1 because it limit the enzyme obtained or obtainable from a marine organism to hexose oxidase; and claim 5 further limits claim 4 to hexose oxidase of SEQ ID NO: 1 or a variant, homologue, or fragment thereof having at least 75% homology with SEQ ID NO: 1.

Applicants' arguments filed 2/25/04 have been fully considered, but they are found unpersuasive. The claim as amended is confusing because SEQ ID NO: 1 is not an amino acid sequence. It is a nucleic acid sequence. Assuming that applicants intended to say SEQ ID NO: 2, the claim is still improperly dependent from claim 4 because it expands the scope of the claim from which it depends. The phrases variants, homologue, derivative or fragment reads on any enzyme having the same activity from any biological species and mutants thereof. Applicants should be reminded that claims 1 and 4 are limited to wild-type enzyme obtained from a marine organism.

Applicant is advised that should claim 22 be found allowable, claim 24 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof for the reasons set forth in the prior Office action, mailed November 25, 2003.

Applicant is advised that should claim 26 be found allowable, claim 28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof for the reasons set forth in the prior Office action, mailed November 25, 2003.

In response to the above objections, Applicants traverse the objections on the ground that claims 22 and 24, and claims 26 and 28 have different scope.

Applicants' arguments filed 2/25/04 have been fully considered, but they are found unpersuasive. Claims 22 and 24 as well as 26 and 28 limit the composition to a chemical compound with a specific structure, i.e., presumably, SEQ ID NO: 2. It does not matter what is the source of the chemical compound is or the method by which said chemical compound is made.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the

terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-16, 21, 23, 25, and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed for the reasons set forth in the prior Office action, mailed November 25, 2003

Applicants argue that disclosure describes enzymes other than hexose oxidase on page 7, lines 3-8, combination of enzymes and substrates on page 15, lines 4-8, and the assay described on page 22, lines 1-2 is adoptable to any oxidase.

Applicants' arguments filed 2/25/04 have been fully considered but they are not deemed to be persuasive. While the applicants are correct of the teaching of the specification, the specification fails to identify a structural feature that is attributable to any of the stated enzymatic activities identified on page 7, line 3-8, wherein the enzyme is obtained or obtainable from a marine organism except for the hexose oxidase of SEQ ID NO: 2. Since the applicants have not described any structural feature for any of the enzymes in general or any other hexose oxidase other than that of SEQ ID NO: 2, the claims remain rejected. Claims directed to a composition comprising the hexose oxidase of SEQ ID NO: 2 would overcome this rejection.

Claims 1-16, 21, 23, 25, and 27 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to an anti-fouling composition comprising *Chondrus crispus* hexose oxidase of SEQ ID NO: 2, and any of its known substrate listed in the specification for the reasons set forth in the prior Office action, mailed November 25, 2003.

Applicants argue that disclosure enabled the claimed invention without undue experimentation.

Applicants' arguments filed 2/25/04 have been fully considered but they are not deemed to be persuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely assert that "the specification provides one of ordinary skill in the art with sufficient guidance to make

10, last full paragraph." Applicants make no effort to explain why they consider the disclosure of the *Chondrus crispus* hexose oxidase of SEQ ID NO: 2 is sufficient enabling for redesigning 25% of the amino acid sequence of SEQ ID NO: 2 or for any glucose, sugar or amino acid oxidase from any marine organism. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-16 and 21-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) The phrase "precursor enzyme" in claims 1, 8, 9, and 16 renders the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired for the reasons set forth in the prior Office action, mailed November 25, 2003.

Applicants argue that they had to use the phrase "precursor enzyme" to distinguish it from the other enzyme in the claim.

Applicants' arguments filed 2/25/04 have been fully considered, but they are not deemed to be persuasive. The phrase "precursor enzyme" means a zymogene or proenzyme. Any other meaning is repugnant to one of ordinary skill in the art. There are many way to distinguish two enzymes in the same claim such as "the substrate-generating enzyme", or numerical or alphabetical attachment to the word enzyme such as enzyme (a) and enzyme (b).

- (b) The phrase "obtained or obtainable" in claims 1-3, 16, and 21-28 renders the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired for the reasons set forth in the prior Office action, mailed November 25, 2003.

Applicants argue that there are many ways to make enzymes that include obtaining the enzyme from its natural source such as marine organisms or a marin enzyme obtained by recombinant methods.

Applicants' arguments filed 2/25/04 have been fully considered, but they are not deemed to be persuasive. The U. S. Patent and Trademark Office has

regardless of the method by which it is made. In fact, removing the phrase "obtained or obtainable" from the claim would not change the scope of the claim, but would obviate this rejection.

- (c) The phrase "or a variant, homologue, derivative or fragment thereof" in claim 5 renders the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired for the reasons set forth in the prior Office action, mailed November 25, 2003.

Applicants argue that the amendment of the claim to define the phrase as 75% of SEQ ID NO: 1 should obviate the rejection.

Applicants' arguments filed 2/25/04 have been fully considered, but they are not deemed to be persuasive. The amendment to the claim has made the claim even more confusing because SEQ ID NO: 1 is not an amino acid sequence. The specification defines the phrase "homologous sequence" on page 10, line 13 and 14, as "taken to include an amino acid sequence which is at least, 75, 85 or 90% identical, at the amino acid level over at least, for example, the amino acid sequence as set out in SEQ ID NO: 2". While the word "homologue" is defined by the claims and the specification, the words variant and derivatives are not.

New Rejection under 35 U.S.C. 112, second paragraph:

- (e) The reference to amino acid sequence of "SEQ ID NO: 1" in claims 5, 22, 24, 26, 28, and 29 renders the claims indefinite and confusing because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. SEQ ID NO: 1 is a nucleic acid sequence, which encodes the amino acid sequence of SEQ ID NO: 2. For examination purposes only, it is assumed that the applicant is referring to SEQ ID NO: 2 only.
- (f) Claims 4, 7, 10-15, and 29 are included with these rejections because they are dependent on rejected claims and do not cure their deficiencies.

The following is a quotation of 35 U.S.C. 103, which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-16 and 21-29 are rejected under 35 U.S.C. 103 as being unpatentable over (IDS: reference AF, EP-0866103 A1) in view of Hansen *et al.* [J. Biol. Chem. 272 (17), April 25, 1997, pages 11581-11587] for the reasons set forth in the prior Office action, mailed November 25, 2003.

Claims 1-16, 21, 23, 25, and 27 are rejected under 35 U.S.C. 103 as being unpatentable over Hamade *et al.* (IDS: reference AF, EP-0866103 A1) in view of U. S. Patent 6,251,626 B1 [626 patent, Stougaard *et al.*] for the reasons set forth in the prior Office action, mailed November 25, 2003.

In response to the above rejections, Applicants argue that Hamade *et al.* does not teach antifouling composition, and Hansen *et al.* and Stougaard *et al.* do not relate hexose oxidase to antifouling composition.

Applicants' arguments filed 2/25/04 have been fully considered but they are not deemed to be persuasive. Applicants are mistaken about the teaching of Hamade *et al.* Hamade *et al.* teach antifouling composition through the release of hydrogen peroxide by the action of glucose oxidase on glucose in the presence of oxygen. Hydrogen peroxide has adverse effect on marine organisms among others.

Hamade *et al.* teach a method preventing fouling surfaces submerged in water by in which an anti-fouling agent is produced by an enzyme action on its substrate, and anti-fouling composition comprising an enzyme and its substrate, see abstract. They specifically teach an enzyme substrate combination capable of producing hydrogen peroxide and exemplify the enzyme-substrate combination with glucose oxidase-glucose and hexose oxidase-glucose, see page 5, lines 14-22. In addition, they teach that the substrate of said oxidase can be produced within the composition by a second enzyme action on a precursor substrate such as the action of cellulase on cellulose to

composition and method except that they did not teach the enzyme from a marine organism. Both Hansen *et al.* and Stougaard *et al.* provide motivation to one of ordinary skill in the art to use the hexose oxidase from *C. crispus* as they suggest that the hexose oxidase from *C. crispus* would be a superior substitute for glucose oxidase because of its broader substrate specificity. The prior art has the teaching of antifouling composition comprising glucose oxidase and hexose oxidase from *Chondrus crispus* as well as the suggestion that the hexose oxidase has broader substrate selectivity and is a superior substitute for glucose oxidase. One of ordinary skill in the art would have had the expectation of success in his knowledge of the fact that the effective ingredient in the antifouling agent is the hydrogen peroxide which is produced by the action of both glucose oxidase and hexose oxidase, and the suggestion of Hansen *et al.* and Stougaard *et al.* that hexose oxidase is a superior substitute to glucose oxidase. Thus, a *prima facie* case of obviousness is established, and therefore, the claims remain rejected.

No claim is allowed.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
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